K020479

MAR 2 6 2002

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5 Nellcor Compatible Saturation Module, M-NSAT and accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

February 9, 2002

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5 Nellcor Compatible Saturation Module, M-NSAT and accessories

COMMON NAME:

Pulse oximeter

CLASSIFICATION NAME:

The following Class II classification appears applicable:

DQA	Oximeter	870.2700
DPZ	Ear Oximeter	870.2710

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The new Datex-Ohmeda S/5 Nellcor Compatible Saturation Module, M-NSAT is substantially equivalent in safety and effectiveness to the legally marketed (predicate) AS/3 Nellcor Compatible Saturation Module, M-NSAT (K943456).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The intended and indications for use for the modified device is the same as the predicate (K943456).
There has been no change to the fundamental scientific technology from the predicate.

The device description of the S/5 Nellcor Compatible Saturation Module M-NSAT is as follows:
□ a single width plug-in module of the S/5 multiparameter monitor
□ measuring noninvasive arterial oxygen saturation and pulse rate
□ sensor consists two light wavelenghts LEDs and photodetector
□ Nellcor OEM SpO2 measurement board MP 404 and accessories
□ an interface board for connecting the measurement board to the monitor

The modifications to the device are:
1. The Nellcor measurement board MP 203/204 is changed to Nellcor measurement board MP 404.
2. The interface board was modified to incorporate an interface for the Nellcor MP 404 board.
3. The interface software of the interface board was modified to incorporate an interface for the Nellcor MP 404 software.
4. The D-9 patient connector of the module is changed to the new pre-amplifier board circuit including the new patient connector model. These changes are determinate by Nellcor as part of the MP 404 specification.
5. Mechanics of the module bezel is redesigned for the new Nellcor patient connector and the pre-amplifier board.
6. The accessories of the new module are extended to the whole Nellcor sensor line as part of the MP 404 technology.
7. The new Nellcor trunk cable MC-10 is used.

The Datex-Ohmeda S/5 Nellcor Compatible Saturation Module, M-NSAT and accessories (later referred to as M-NSAT) is a module used to monitor arterial oxygen saturation. The user interface has been implemented in the main software of the
AS/3 Anesthesia Monitor
or AS/3 Compact Monitor using S-STDxx or S-ARKxx software
or CS/3 Monitors using S-ICUxx software
or S/5 Anesthesia Monitor
or S/5 Critical Care monitor
or S/5 Compact Anesthesia Monitor
or S/5 Compact Critical Care Monitor

The M-NSAT module provides continuos non-invasive measurement of the pulse rate and oxygen saturation. Visual and auditory alarms are given for high/low pulse rate and high/low saturation values. The user can adjust alarm limits.
The M-NSAT module is designed using the Nellcor pulse oximetry technology. The user interface of the new M-NSAT module revision –04 is equivalent to the M-NSAT Nellcor Compatible Saturation Module (K943456).

INTENDED USE as required by 807.92(a)(5)

The Datex-Ohmeda S/5 TM Nellcor Compatible Saturation Module, M-NSAT is intended for use with the Datex-Ohmeda modular multiparameter patient monitors for monitoring arterial oxygen saturation of hospitalized patients.

Indication for use:
The Datex-Ohmeda S/5 TM Nellcor Compatible Saturation Module, M-NSAT, and accessories are indicated for monitoring arterial oxygen saturation of hospitalized patients. The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The new Datex-Ohmeda S/5 Nellcor Compatible Saturation Module, M-NSAT is substantially equivalent in safety and effectiveness to the legally marketed (predicate) AS/3 Nellcor Compatible Saturation Module, M-NSAT (K943456).

The redesigned M-NSAT module has the following similarities compared to the M-NSAT predicate device.
- ☐ identical intended use and indications for use
- ☐ identical fundamental scientific technology
- ☐ have the same indicated use,
- ☐ use the same operating principle
- ☐ have the same safety and effectiveness
- ☐ have the same user interface and alarms
- ☐ are manufactured using the same processes

The main differences between the new M-NSAT and the predicate is primarily due to fact that the new M-NSAT uses
- ☐ the new measurement board MP 404
- ☐ the modified interface board
- ☐ the modified interface software
- ☐ the new pre-amplifier board and the patient connector
- ☐ the new bezel
- ☐ the whole Nellcor's sensor line accessories
- ☐ the trunk cable MC-10

The new Datex-Ohmeda S/5 Nellcor Compatible Saturation Module, M-NSAT and AS/3 Nellcor Compatible Saturation Module, M-NSAT (K943456) have the same intended use and Indication for use. The new M-NSAT and the M-NSAT (K943456) are intended for use with the Datex-Ohmeda modular multiparameter patient monitors for monitoring arterial oxygen saturation of hospitalized patients. Both are indicated for use by qualified medical personnel only. The new Datex-Ohmeda S/5 Nellcor Compatible Saturation Module, M-NSAT and AS/3 Nellcor Compatible Saturation Module, M-NSAT (K943456) uses the same user interface and alarm logic of the monitor. The data of both modules are receiving and showing on the monitor screen similar. Alarms of both modules have the same alarm menus and alarms can be adjusted equally.

In summary, the Nellcor Compatible Saturation Module, M-NSAT, described in this submission is substantially equivalent to the predicate device.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5 Nellcor Compatible Saturation Module, M-NSAT and accessories complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- 21 CFR 898.12 – Performance Standard for Electrode Lead Wires and Patient Cables
- ANSI/AAMI ES1-1993
- IEC60601-1:1988, Amendment 1: 1991, Amendment 2: 1995
- EN 60601-1:1990 +A1:1993 +A2:1995 +A13:1996
- UL 2601-1 : 1997
- IEC 60601-1-2
- IEC 60601-1-4

Conclusion:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5 Nellcor Compatible Saturation Module, M-NSAT and accessories as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2002

Mr. Joel C. Kent
Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492

Re: K020479
Datex-Ohmeda S/5™ Nellcor compatible Saturation Module, M-NSAT and accessories
Regulation Number: 870.2700, 870.2710
Regulation Name: Oximeter, Ear Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA, 74 DPZ
Dated: March 13, 2002
Received: March 14, 2002

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020479

Device Name: Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, M-NSAT, and accessories

The Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, M-NSAT, and accessories are indicated for monitoring arterial oxygen saturation of hospitalized patients. The device is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020479